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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,164	04/23/2001	Vladimir Kozlov	1331-338	6786

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Nixon & Vanderhye P.C.
8th Floor
1100 N. Glebe Rd.
Arlington, VA 22201

EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1653	12

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,164	KOZLOV ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

This Office Action is in response to Paper #10, filed March 19, 2003. Claims 30-32 are currently pending and are under examination.

Withdrawal of Rejections

The rejection of Claim 29 and 32 under 35 U.S.C. 102(e) as being anticipated by Estep (USP 4,861,867) is withdrawn.

Maintenance of Rejections

Claim 30-32 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 30-32 are indefinite because it is not clear what present in the milligram amounts means, as a composition comprises a concentration of a particular item, such as grams/liter, for example.

Applicants argue that the composition has 0.1 mg to 6 g of the recited globin chain, regardless of the concentration and thus there is no ambiguity as to whether a given composition is included or excluded from the claim. Further, that no authority or reason has been given for the assertion that the recitation of amounts is not permitted in claims directed to compositions. It is standard chemical and pharmaceutical practice to recite concentrations when discussing compositions. One need only look at the label of a solution of over-the-counter drugs to see this practice, or even the claims of Applicant's USP 5,939,391. Is Applicant implying that 0.1 mg of globin chain in a room full of pharmaceutical carrier is the same as 0.1 mg of globin chain in a milliliter of pharmaceutical carrier? Essential elements in a solution are presented as a concentration, not as an amount. It appears that Applicants may be wanting to administer 0.1 mg to 6 g of globin chain to a subject in a single dose. However, that is not what is

being claimed. Rather, any part of that pharmaceutical composition can be administered. Therefore, this rejection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 30-32 are again rejected under 35 U.S.C. 102(b) as being anticipated by Tame et al. (1991; J. Mol. Biol. 218:761-767). Tame et al. teach alpha -globin in a buffer solution, which is a pharmaceutically acceptable carrier (page 763, col. 1, para. 1). This alpha -globin was diluted to 5 mg/ml with the buffer and then diluted further to 0.25 mg/ml with a potassium buffer. Beta-globin was added to the alpha -globin solution in the presence of hemin dicyanide. The beta-globin added to the alpha -globin solution was most likely in the same buffer as the alpha -globin because it was added in "molar excess", indicating that the beta-globin was in solution and in at least the concentration of the alpha -globin. Claims 30 to 32 are anticipated because there is no concentration provided in the claims, and enough of the solutions taught in Tame et al. can be made to comprise 0.1 mg to 6 g of globin. For example, 1 ml of the alpha globin solution at either 5 mg/ml or 0.25 mg/ml would meet the amount of globin in the solution claimed.

Applicants argue that Tame et al. do not disclose whether the beta globin was in a pharmaceutically acceptable carrier and that it is impermissible to assume as to how the beta globin solution was made. When one skilled in the art mixes two solutions, the base solution is the

same. Therefore, the assumption that the beta globin was in the same solution as the alpha globin is not impermissible.

Applicants argue that Tame et al. do not disclose whether the solution of alpha and of beta globin was pharmaceutically acceptable. The buffers recited in Tame et al. are pharmaceutically acceptable. Applicants have not provided any evidence that these buffers are not pharmaceutically acceptable. Therefore, this argument is not persuasive.

Applicants argue that Tame et al. do not disclose the recited amount of globin chain; thus, because Tame et al. do not disclose the making of a solution containing from 0.1 mg to 6 g of globin chain, Tame et al. do not anticipate the claims. Just the single milliliter of Tame et al.'s solution meets the claim amount recitation; it is not clear what exactly Applicant is arguing. For example, Claim 31 reads that a composition will consist essentially of alpha globin in a pharmaceutically acceptable carrier. So, alpha globin is the active ingredient and anything else is inert or nonessential. This jug/beaker/vial/syringe of solution must have the alpha globin chain present in 0.1 mg to 6 g. The composition must be suitable for subcutaneous administration, meaning it can be administered s.c. There is no recitation that the composition in total comprise 6 g of alpha chain in an amount of carrier for single dose s.c. injections. And even if it did, 1 ml of Tame et al.'s solution would meet this claim limitation.

Claims 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoffman et al. (USP 5,449,759). Hoffman et al. teach alpha -globin diluted to 0.3 mg/ml potassium phosphate buffer, which is a pharmaceutically acceptable carrier (col. 18, line 28; Claim 30). Beta -globin, dissolved in a tris buffer solution at 5 mg/ml (col. 18, line 25; Claim 31), was added to this alpha -globin (col. 18, line 36; Claim 32). Claims 30 to 32 do not recite a concentration and enough of the solutions taught in Hoffman et al. can be made to comprise 0.1 mg to 6 g of globin.

Applicants argue that Hoffman et al. do not disclose the recited amount of globin chain; thus, because Hoffman et al. do not disclose the making of a solution containing from 0.1 mg to 6 g of globin chain, Hoffman et al. do not anticipate the claims. Just the single milliliter of Hoffman et al.'s solution meets the claim amount recitation; it is not clear what exactly Applicant is arguing. For example, Claim 31 reads that a composition will consist essentially ot alpha globin in a pharmaceutically acceptable carrier. So, alpha globin is the active ingredient and anything else is inert or nonessential. This jug/beaker/vial/syringe of solution must have the alpha globin chain present in 0.1 mg to 6 g. The composition must be suitable tor subcutaneous administration, meaning it can be administered s.c. There is no recitation that the composition in total comprise 6 g of alpha chain in an amount ot carrier tor single dose s.c. injections. And even if it did, 1 ml ot Hoffman et al.'s solution would meet this claim limitation.

There is sufficient evidence that the product disclosed by the reference is Applicants' product, and the burden is shifted to Applicants to distinguish the two. See *In re Best*, 195 USPQ 430 and *Ex Parte Gray* 10 USPQ 2d 1922, 1923.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the

date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER